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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/619,649	DRMANAC, RADOJE	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *97 and 157-176* is/are pending in the application.

4a) Of the above claim(s) *176* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *97 and 157-175* is/are rejected.

7)☒ Claim(s) *160 and 170* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 April 1996* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group III in the reply filed on 16 December 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's cancellation of Claims 1-96 and 98-156 is acknowledged.

Applicant has added Claims 157-176.

Newly submitted claim 176 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: New Claim 176 is drawn to a method similar to that of non-elected Group I.

Since applicant has elected the invention of Group III, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 176 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 97 and 157-175 are under consideration.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Multiple Arrays on a Support

Claim Objections

3. Claims 160 and 170 are objected to because of the following informalities: The claims both use incorrect syntax i.e. "are positioned for used".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 97 and 157-165 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the Preliminary Amendment filed 23 April 1997, Claim 97 was added. Claim 97 is drawn to an array of "microchips". The specification as originally filed does not teach or describe the claimed "microchips" so as to reasonably convey to one skilled in the art the meets and bounds of the claim. Therefore, the term "microchip" constitutes new matter.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 97, 159-160, 163-166, 169-170 and 173-175 are rejected under 35 U.S.C. 102(b) as being anticipated by Southern et al (Genomics, 1992, 13: 1008-1017).

Regarding Claim 97, Southern et al disclose a support comprising an array of microchips, each having an array of oligonucleotide probes immobilized thereon (Fig. 3, figure legend, line 1).

Regarding Claim 159, Southern et al disclose the support wherein the microchips are arranged in multiple rows and columns (i.e. two rows and two columns, Fig. 3).

Regarding Claim 160, Southern et al disclose the support wherein the microchips are positioned for use with a multichannel pipet (Fig. 3). The arrays of Southern are arranged in two rows of two columns. While Southern does not teach use of a multichannel pipet, the courts have stated that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Southern teaches the structural elements of the claim and therefore, anticipates the support of Claim 160.

Regarding Claim 163, Southern et al disclose the support wherein the array of microchips comprises more than 256 probes i.e. each of the four microchips has 256 probes. Hence, the support of Claim 97 has more than 256 probes per array as claimed.

Regarding Claim 164, Southern et al disclose the support wherein the probes are between 4 and 9 bases (Fig. 3).

Regarding Claim 165, Southern et al disclose the support wherein the probes are synthesized on the support (page 1009, left column). Southern et al do not teach light-directed synthesis. However, the courts have stated that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113. Because determination of patentability is based on the product and because Southern et al teach the product, the process of making the product as recited in the claim does not define the product over that of Southern.

Regarding Claim 166, Southern et al disclose a support comprising an array of microchips, each having an array of oligonucleotide probes immobilized thereon (Fig. 3, figure legend, line 1).

Regarding Claim 169, Southern et al disclose the support wherein the microchips are arranged in multiple rows and columns (i.e. two rows and two columns, Fig. 3).

Regarding Claim 170, Southern et al disclose the support wherein the microchips are positioned for use with a multichannel pipet (Fig. 3). The arrays of Southern are arranged in two rows of two columns. While Southern does not teach use of a multichannel pipet, the courts have stated that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). Southern teaches the structural elements of the claim and therefore, anticipates the support of Claim 160.

Regarding Claim 173, Southern et al disclose the support wherein the array of microchips comprises more than 256 probes i.e. each of the four microchips has 256 probes. Hence, the support of Claim 97 has more than 256 probes per array as claimed.

Regarding Claim 174, Southern et al disclose the support wherein the probes are between 4 and 9 bases (Fig. 3).

Regarding Claim 175, Southern et al disclose the support wherein the probes are synthesized on the support (page 1009, left column). Southern et al do not teach light-directed synthesis. However, the courts have stated that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113. Because determination of patentability is based on the product and because Southern et al teach the product, the process of making the product as recited in the claim does not define the product over that of Southern.

8. Claims 97, 157-160, 163-170 and 173-175 are rejected under 35 U.S.C. 102(e) as being anticipated by Winkler et al (U.S. Patent No. 5,677,195, filed 20 November 1992).

Regarding Claim 97, Winkler et al disclose a support comprising an array of microchips, each having an array of oligonucleotide probes immobilized thereon (i.e. the support comprises an array of regions (#1004) wherein each region comprises an array (i.e. plurality) of probes immobilized thereon (Column 7, lines 10-41; Column 16, lines 22-53; and Fig. 12). Winkler et al define the region as having a predominate species of probe (Column 7,

lines 31-38). In other words, the region has an array of probes immobilized thereon as recited in the instant claims.

Regarding Claim 157, Winkler et al disclose the support wherein the microchips are separated by physical barriers (Column 22, lines 8-14).

Regarding Claim 158, Winkler et al disclose the support wherein the microchips are separated by hydrophobic surface (Column 22, lines 8-14).

Regarding Claim 159, Winkler et al disclose the support wherein the microchips are arranged in multiple rows and columns (Fig. 12).

Regarding Claim 160, Winkler et al disclose the support wherein the microchips are positioned for use with a multichannel pipet (Column 18, lines 20-37 and Column 20, lines 34-40).

Regarding Claim 163, Winkler et al disclose the support wherein the array of microchips comprises more than 256 probes i.e. more than 256 regions (Column 17, lines 49-53).

Regarding Claim 164, Winkler et al disclose the support wherein the probes are between 4 and 9 bases (Column 17, lines 55-57).

Regarding Claim 165, Winkler et al disclose the support wherein the probes are synthesized on the support via light-directed synthesis (Abstract).

Regarding Claim 166, Winkler et al disclose a support comprising an array of microchips, each having an array of oligonucleotide probes immobilized thereon (i.e. the support comprises an array of regions (#1004) wherein each region comprises an array (i.e. plurality) of probes immobilized thereon (Column 7, lines 10-41; Column 16, lines 22-53; and Fig. 12). Winkler et al define the region as having a predominate species of probe (Column 7, lines 31-38). In other words, the region has an array of probes immobilized thereon as recited in the instant claims.

Regarding Claim 167, Winkler et al disclose the support wherein the microchips are separated by physical barriers (Column 22, lines 8-14).

Regarding Claim 168, Winkler et al disclose the support wherein the microchips are separated by hydrophobic surface (Column 22, lines 8-14).

Regarding Claim 169, Winkler et al disclose the support wherein the microchips are arranged in multiple rows and columns (Fig. 12).

Regarding Claim 170, Winkler et al disclose the support wherein the microchips are positioned for use with a multichannel pipet (Column 18, lines 20-37 and Column 20, lines 34-40).

Regarding Claim 173, Winkler et al disclose the support wherein the array of microchips comprises more than 256 probes i.e. more than 256 regions (Column 17, lines 49-53).

Regarding Claim 174, Winkler et al disclose the support wherein the probes are between 4 and 9 bases (Column 17, lines 55-57).

Regarding Claim 175, Winkler et al disclose the support wherein the probes are synthesized on the support via light-directed synthesis (Abstract).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 162 and 172 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler et al (U.S. Patent No. 5,677,195, filed 20 November 1992) in view of Augenlicht (U.S. Patent No. 4,981,783, issued 1 January 1991).

Regarding Claims 162 and 172, Winkler et al disclose a support comprising an array of microchips, each having an array of oligonucleotide probes immobilized thereon (i.e. the support comprises an array of regions (#1004) wherein each region comprises an array (i.e. plurality) of probes immobilized thereon (Column 7, lines 10-41; Column 16, lines 22-53; and Fig. 12). Winkler et al define the region as having a predominate species of probe (Column 7, lines 31-38). In other words, the region has an array of probes immobilized thereon as recited in the instant claims.

Winkler et al further teach the support is produced using a conventional pipetting instrument (Column 20, lines 34-40) but they are silent regarding an 8 by 12 format. However, Augenlicht teach pipetting instruments wherein the preferred instruments produce an 8 by 12 pattern (Column 13, lines 55-60). Augenlicht further teach these instruments are preferred because they are automated and produce precisely defined positions. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the 8 by 12 format of Augenlicht to the arrays of Winkler et al for the expected benefit of providing precisely defined regions as desired in the art (Augenlicht, Column 13, lines 55-60).

11. Claims 161 and 171 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler et al (U.S. Patent No. 5,677,195, filed 20 November 1992) in view of Stratagene, 1988, page 39).

Regarding Claims 161 and 171, Winkler et al disclose a support comprising an array of microchips, each having an array of oligonucleotide probes immobilized thereon (i.e. the

support comprises an array of regions (#1004) wherein each region comprises an array (i.e. plurality) of probes immobilized thereon (Column 7, lines 10-41; Column 16, lines 22-53; and Fig. 12). Winkler et al define the region as having a predominate species of probe (Column 7, lines 31-38). In other words, the region has an array of probes immobilized thereon as recited in the instant claims.

Winkler et al further teach the array is used with labeled probes and buffers for hybridization analysis (Column 25, lines 6-30) but they are silent regarding the array and hybridization components combined into a kit format.

However, Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method of Winkler et al into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. 2) The other service provided in a kit is quality control" (page 39, column 1).

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 97 and 157-175 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,383,742. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an array of arrays. The claim sets merely differ in the arrangement of limitations within the claim sets. For example, instant claim 97 is drawn to an array of arrays while patent claims 6-8 define the array of Claim 1 as having a plurality of array. Therefore, the claim sets are not patentably distinct.

NOTICE TO COMPLY WITH NUCLEIC ACID SEQUENCE RULES

14. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

APPLICANT IS A PERIOD OF TIME THAT IS CO-EXTENSIVE WITH THE TIME TO REPLY TO THE INSTANT OFFICE ACTION WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.R.F. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Conclusion

15. No claim is allowed.

16. The examiner and art unit for this application has changed. Please address future correspondence to BJ Forman, Art Unit: 1634.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
March 6, 2006

Application No.: 8/619,649

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other: _____

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
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